

Notice of Allowability

Application No.

09/736,151

Examiner

Joyce Tung

Applicant(s)

LAAYOUN ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 7/12/2004.
2. ☒ The allowed claim(s) is/are 3, 16 and 40-86 (final claims 1-49).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>11/22/2004</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

The applicant's response filed 7/12/2004 has been entered. Claims 3, 16, and 40-86 are pending.

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Jacob Doughty on November 22, 2004.

2. The application has been amended as follows:

In claim 3, line 2, after "the steps of:" insert -- obtaining a mixture in which the at least one DNA, RNA or chimeric DNA-RNA polymer has been subject to an *in vitro* nucleic acid amplification reaction; --.

In claim 3, line 4, after "DNA-RNA polymer", insert -- in the mixture --.

In claim 3, line 8, after "fragments", delete ", wherein the fragmenting and attaching steps take place in an *in vitro* nucleic acid amplification mixture".

In claim 16, line 2, after "the steps of:" insert -- obtaining a mixture in which the DNA or RNA nucleic acid has been subject to an *in vitro* nucleic acid amplification reaction; --.

In claim 16, line 3, after "said nucleic acid", insert -- in the mixture --.

In claim 16, line 8, after "treating said", delete "aqueous solution" and substitute therefore -- mixture --.

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In claim 16, line 10, after “labeling agent in the”, delete “aqueous solution” and substitute therefore – mixture --.

In claim 16, line 11, after “dilutes”, delete “an in vitro nucleic acid amplification” and substitute therefore – the --.

3. The following is an examiner’s statement of reasons for allowance:

Concerning claims 3, 16 and 40-86, no prior art has been found teaching or suggesting the method for fragmenting and labeling synthetic or natural DNA, RNA or chimeric DNA-RNA polymer in which the method applies chemically fragmenting the DNA, RNA or chimeric DNA-RNA polymer in the presence of at least one multivalent metal cation in an aqueous solution to produce a plurality of DNA or RNA fragments having freed terminal phosphates and then attaching a labeling agent on the plurality of the fragments at freed terminal phosphates located at the 3’ and/or 5’ end of the fragment, then subjecting to an *in vitro* nucleic acid amplification.

The closest prior art is the references of Morrow (5,684,149) in view of Mirzabekov et al. (5,981,734). Morrow et al. disclose a method to fragment RNA in the presence of a metal complexes (See the Abstract). The metal complexes can promote the cleavage of RNA (See column 6, lines 34-37). Mirzabekov et al. disclose a method for labeling oligonucleotide molecules in which fragmented DNA and RNA are labeled with fluorescence dye (See column 5, lines 4-14, 29-31). However, neither Morrow nor Mirzabekov et al. disclose fragmenting and labeling DNA, RNA or chimeric DNA-RNA polymer in an in vitro amplification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *JW*
December 14, 2004

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
12/16/04